IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of
Tsokos, et al.

Group Art Unit: 1635

Serial No.: 10/772,704

Examiner: Chong, K.

Filed: February 5, 2004

Confirmation number: 5604

FOR: NOVEL METHOD FOR THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSIS

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REPLY BRIEF

Hon. Commissioner of Patents
and Trademarks
PO Box 1450
Alexandria, VA 22313

Sir:

Responsive to the Examiner's Answer dated September 28, 2009, please consider this Reply Brief.

REMARKS

The Examiner's comments are incorrect. The Examiner has not addressed the fact that CREM is a naturally occurring compound in the human body. The Examiner assumes that inhibiting CREM production in a human would not have a deleterious effect. This assumption cannot be made without undue experimentation. The Examiner considers the regulation of immunity factors a simple matter. Nothing could be farther from the truth when it comes to the complex mechanisms and pathways of endocrinology.

Further, the main reference of Solomou et al. leaves a lot to speculation because it is a very early study. Solomou et al. uses words like "possible" and "probably" when it speaks of the role of CREM and IL-2 transcription. In fact, one of ordinary skill in the art would have only considered Solomou et al. an early study and not directive. Solomou et al states at page 4221, col. 2 that "it is *possible* that p-CREM exhibits higher DNA binding affinity than p-CREB, resulting in occupation of the -180° site in SLE and subsequent repression of the IL-2 transcription. Regulation of IL-2 transcription is complex, and its decreased transcription in SLE T cells is *probably* multifactorial."

The Examiner has not taken into consideration that eliminating CREM production may not have resulted in normal IL-2 production in SLE patients. Moreover, one of ordinary skill in the art at the time of the invention would not have determined based on Solomou et al. that reducing or eliminating CREM production would have resulted in normal IL-2 production or a cure for SLE.

For these reasons, Appellant respectfully submits that Solomou, et al. would not have lead one of ordinary skill in the art to arrive at the present invention. The

Examiner's justification is based on hindsight. Solomou et al. provides speculation on the basis of deficient IL-2 production in SLE patients and teaches that the solution to solving the problem is complex and multifactorial. With so much of the science unknown at the time of Solomou et al, it cannot serve as a basis for the combination with the other references to arrive at the present invention.

Reconsideration and the granting of this appeal is respectfully requested.

Respectfully submitted,

Date: Oct. 21, 2009 By

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